

EXHIBIT 19

EXAMINATION OF APPLICATIONS

716.10

Affidavits or declarations presented to show that the disclosure of an application is sufficient to one skilled in the art are not acceptable to establish facts which the specification itself should recite. *In re Buchner*, 929 F.2d 660, 18 USPQ2d 1331 (Fed. Cir. 1991) (Expert described how he would construct elements necessary to the claimed invention whose construction was not described in the application or the prior art; this was not sufficient to demonstrate that such construction was well-known to those of ordinary skill in the art.); *In re Smyth*, 189 F.2d 982, 90 USPQ 106 (CCPA 1951).

Affidavits or declarations purporting to explain the disclosure or to interpret the disclosure of a pending application are usually not considered. *In re Oppenauer*, 143 F.2d 974, 62 USPQ 297 (CCPA 1944). But see *Glaser v. Strickland*, 220 USPQ 446 (Bd. Pat. Int. 1983) which reexamines the rationale on which *In re Oppenauer* was based in light of the Federal Rules of Evidence. The Board stated as a general proposition “Opinion testimony which merely purports to state that a claim or count, is ‘disclosed’ in an application involved in an interference . . . should not be given any weight. Opinion testimony which purports to state that a particular feature or limitation of a claim or count is disclosed in an application involved in an interference and which explains the underlying factual basis for the opinion may be helpful and can be admitted. The weight to which the latter testimony may be entitled must be evaluated strictly on a case-by-case basis.”

716.10 Attribution

Under certain circumstances an affidavit or declaration may be submitted which attempts to attribute an activity, a reference or part of a reference to the applicant. If successful, the activity or the reference is no longer applicable. When subject matter, disclosed but not claimed in a patent application filed jointly by S and another, is claimed in a later application filed by S, the joint patent or joint patent application publication is a valid reference available as prior art under 35 U.S.C. 102(a), (e), or (f) unless overcome by affidavit or declaration under 37 CFR 1.131 showing prior invention (see MPEP § 715) or an unequivocal declaration by S under 37 CFR 1.132 that he or she conceived or invented the subject matter disclosed in the patent or published application. Disclaimer by the

other patentee or other applicant of the published application should not be required but, if submitted, may be accepted by the examiner.

Where there is a published article identifying the authorship (MPEP § 715.01(c)) or a patent or an application publication identifying the inventorship (MPEP § 715.01(a)) that discloses subject matter being claimed in an application undergoing examination, the designation of authorship or inventorship does not raise a presumption of inventorship with respect to the subject matter disclosed in the article or with respect to the subject matter disclosed but not claimed in the patent or published application so as to justify a rejection under 35 U.S.C. 102(f).

However, it is incumbent upon the inventors named in the application, in response to an inquiry regarding the appropriate inventorship under 35 U.S.C. 102(f) or to rebut a rejection under 35 U.S.C. 102(a) or (e), to provide a satisfactory showing by way of affidavit under 37 CFR 1.132 that the inventorship of the application is correct in that the reference discloses subject matter derived from the applicant rather than invented by the author, patentee, or applicant of the published application notwithstanding the authorship of the article or the inventorship of the patent or published application. *In re Katz*, 687 F.2d 450, 455, 215 USPQ 14, 18 (CCPA 1982) (inquiry is appropriate to clarify any ambiguity created by an article regarding inventorship and it is then incumbent upon the applicant to provide “a satisfactory showing that would lead to a reasonable conclusion that [applicant] is the ... inventor” of the subject matter disclosed in the article and claimed in the application).

An uncontradicted “unequivocal statement” from the applicant regarding the subject matter disclosed in an article, patent, or published application will be accepted as establishing inventorship. *In re DeBaun*, 687 F.2d 459, 463, 214 USPQ 933, 936 (CCPA 1982). However, a statement by the applicants regarding their inventorship in view of an article, patent, or published application may not be sufficient where there is evidence to the contrary. *Ex parte Kroger*, 218 USPQ 370 (Bd. App. 1982) (a rejection under 35 U.S.C. 102(f) was affirmed notwithstanding declarations by the alleged actual inventors as to their inventorship in view of a nonapplicant author submitting a letter declaring the author’s inventorship); *In re Carreira*, 532 F.2d 1356, 189 USPQ 461 (CCPA 1976) (dis-

claiming declarations from patentees were directed at the generic invention and not at the claimed species, hence no need to consider derivation of the subject matter).

A successful 37 CFR 1.132 affidavit or declaration establishing derivation by the author, patentee, or applicant of the published application of a first reference does not enable an applicant to step into the shoes of that author, patentee, or applicant of the published application in regard to its date of publication so as to defeat a later second reference. *In re Costello*, 717 F.2d 1346, 1350, 219 USPQ 389, 392 (Fed. Cir. 1983).

EXAMPLES

The following examples demonstrate the application of an attribution affidavit or declaration.

Example 1

During the search the examiner finds a reference fully describing the claimed invention. The applicant is the author or patentee and it was published or patented less than one year prior to the filing date of the application. The reference cannot be used against applicant since it does not satisfy the 1-year time requirement of 35 U.S.C. 102(b).

Example 2

Same facts as above, but the author or patentee is an entity different from applicant. Since the entities are different, the reference is prior art under 35 U.S.C. 102(a) or (e).

In the situation described in Example 2, an affidavit under 37 CFR 1.132 may be submitted to show that the relevant portions of the reference originated with or were obtained from applicant. Thus the affidavit attempts to convert the fact situation from that described in Example 2 to the situation described in Example 1.

718 Affidavit or Declaration to Disqualify Commonly Owned Patent as Prior Art, 37 CFR 1.130 [R-6]

37 CFR 1.130. Affidavit or declaration to disqualify commonly owned patent or published application as prior art.

(a) When any claim of an application or a patent under reexamination is rejected under 35 U.S.C. 103 on a U.S. patent or U.S.

patent application publication which is not prior art under 35 U.S.C. 102(b), and the inventions defined by the claims in the application or patent under reexamination and by the claims in the patent or published application are not identical but are not patentably distinct, and the inventions are owned by the same party, the applicant or owner of the patent under reexamination may disqualify the patent or patent application publication as prior art. The patent or patent application publication can be disqualified as prior art by submission of:

(1) A terminal disclaimer in accordance with § 1.321(c); and

(2) An oath or declaration stating that the application or patent under reexamination and patent or published application are currently owned by the same party, and that the inventor named in the application or patent under reexamination is the prior inventor under 35 U.S.C. 104.

(b) [Reserved]

See MPEP § 804.03 and § 706.02(l) through § 706.02(l)(3) for subject matter disqualified as prior art under 35 U.S.C. 103(c) where the subject matter and the claimed invention were, at the time the invention was made, owned by the same person or subject to an obligation of assignment to the same person.

37 CFR 1.130(a) addresses those situations in which the rejection in an application or patent under reexamination to be overcome is a rejection under 35 U.S.C. 103 in view of a U.S. patent or U.S. patent application publication due to the requirement in 37 CFR 1.131 that any U.S. patent or U.S. patent application publication to be antedated not claim the same patentable invention (as defined in 37 CFR 41.203(a)) as the application or patent under reexamination. The applicant or patent owner is also prevented from proceeding in an interference due to the provision in 37 CFR 41.206 that an interference will not normally be declared or continued between applications that are commonly owned, or an application and an unexpired patent that are commonly owned.

As 37 CFR 1.130(a) addresses those situations in which the inventions defined by the claims in the application or patent under reexamination and by the claims in the U.S. patent or patent application publication are not patentably distinct, 37 CFR 1.130(a)(1) requires a terminal disclaimer in accordance with 37 CFR 1.321(c), and 37 CFR 1.130(a)(2) requires an oath or declaration stating, *inter alia*, that the inventor named in the application or patent under reexamination is the prior inventor under 35 U.S.C. 104. The inventor named in the application or patent under reexamination must have invented the claimed subject

v. *Finney*, 34 F.3d 1058, 1063, 32 USPQ2d 1115, 1120 (Fed. Cir. 1994)).

Thus, while an applicant may on occasion need to provide evidence to show that an invention will work as claimed, it is improper for Office personnel to request evidence of safety in the treatment of humans, or regarding the degree of effectiveness. See *In re Sichert*, 566 F.2d 1154, 196 USPQ 209 (CCPA 1977); *In re Hartop*, 311 F.2d 249, 135 USPQ 419 (CCPA 1962); *In re Anthony*, 414 F.2d 1383, 162 USPQ 594 (CCPA 1969); *In re Watson*, 517 F.2d 465, 186 USPQ 11 (CCPA 1975); *In re Krimmel*, 292 F.2d 948, 130 USPQ 215 (CCPA 1961); *Ex parte Jovanovics*, 211 USPQ 907 (Bd. Pat. App. & Inter. 1981).

VI. TREATMENT OF SPECIFIC DISEASE CONDITIONS

Claims directed to a method of treating or curing a disease for which there have been no previously successful treatments or cures warrant careful review for compliance with 35 U.S.C. 101. The credibility of an asserted utility for treating a human disorder may be more difficult to establish where current scientific understanding suggests that such a task would be impossible. Such a determination has always required a good understanding of the state of the art as of the time that the invention was made. For example, prior to the 1980's, there were a number of cases where an asserted use in treating cancer in humans was viewed as "incredible." *In re Jolles*, 628 F.2d 1322, 206 USPQ 885 (CCPA 1980); *In re Buting*, 418 F.2d 540, 163 USPQ 689 (CCPA 1969); *Ex parte Stevens*, 16 USPQ2d 1379 (Bd. Pat. App. & Inter. 1990); *Ex parte Busse*, 1 USPQ2d 1908 (Bd. Pat. App. & Inter. 1986); *Ex parte Krepelka*, 231 USPQ 746 (Bd. Pat. App. & Inter. 1986); *Ex parte Jovanovics*, 211 USPQ 907 (Bd. Pat. App. & Inter. 1981). The fact that there is no known cure for a disease, however, cannot serve as the basis for a conclusion that such an invention lacks utility. Rather, Office personnel must determine if the asserted utility for the invention is credible based on the information disclosed in the application. Only those claims for which an asserted utility is not credible should be rejected. In such cases, the Office should carefully review what is being claimed by the applicant. An assertion that the claimed invention is useful in treating a symptom of an incurable disease may be considered credible by a person of ordinary

skill in the art on the basis of a fairly modest amount of evidence or support. In contrast, an assertion that the claimed invention will be useful in "curing" the disease may require a significantly greater amount of evidentiary support to be considered credible by a person of ordinary skill in the art. *In re Sichert*, 566 F.2d 1154, 196 USPQ 209 (CCPA 1977); *In re Jolles*, 628 F.2d 1322, 206 USPQ 885 (CCPA 1980). See also *Ex parte Ferguson*, 117 USPQ 229 (Bd. Pat. App. & Inter. 1957).

In these cases, it is important to note that the Food and Drug Administration has promulgated regulations that enable a party to conduct clinical trials for drugs used to treat life threatening and severely-debilitating illnesses, even where no alternative therapy exists. See 21 CFR 312.80-88 (1994). Implicit in these regulations is the recognition that experts qualified to evaluate the effectiveness of therapeutics can and often do find a sufficient basis to conduct clinical trials of drugs for incurable or previously untreatable illnesses. Thus, affidavit evidence from experts in the art indicating that there is a reasonable expectation of success, supported by sound reasoning, usually should be sufficient to establish that such a utility is credible.

2111 Claim Interpretation; Broadest Reasonable Interpretation [R-5]

CLAIMS MUST BE GIVEN THEIR BROADEST REASONABLE INTERPRETATION

During patent examination, the pending claims must be "given their broadest reasonable interpretation consistent with the specification." >The Federal Circuit's *en banc* decision in *Phillips v. AWH Corp.*, 415 F.3d 1303, 75 USPQ2d 1321 (Fed. Cir. 2005) expressly recognized that the USPTO employs the "broadest reasonable interpretation" standard:

The Patent and Trademark Office ("PTO") determines the scope of claims in patent applications not solely on the basis of the claim language, but upon giving claims their broadest reasonable construction "in light of the specification as it would be interpreted by one of ordinary skill in the art." *In re Am. Acad. of Sci. Tech. Ctr.*, 367 F.3d 1359, 1364[, 70 USPQ2d 1827] (Fed. Cir. 2004). Indeed, the rules of the PTO require that application claims must "conform to the invention as set forth in the remainder of the specification and the terms and phrases used in the claims must find clear support or antecedent basis in the description so that the meaning of the terms in the claims may be ascertainable by reference to the description." 37 CFR 1.75(d)(1).

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415 F.3d at 1316, 75 USPQ2d at 1329. See also *In re Hyatt*, 211 F.3d 1367, 1372, 54 USPQ2d 1664, 1667 (Fed. Cir. 2000). Applicant always has the opportunity to amend the claims during prosecution, and broad interpretation by the examiner reduces the possibility that the claim, once issued, will be interpreted more broadly than is justified. *In re Prater*, 415 F.2d 1393, 1404-05, 162 USPQ 541, 550-51 (CCPA 1969) (Claim 9 was directed to a process of analyzing data generated by mass spectrographic analysis of a gas. The process comprised selecting the data to be analyzed by subjecting the data to a mathematical manipulation. The examiner made rejections under 35 U.S.C. 101 and 102. In the 35 U.S.C. 102 rejection, the examiner explained that the claim was anticipated by a mental process augmented by pencil and paper markings. The court agreed that the claim was not limited to using a machine to carry out the process since the claim did not explicitly set forth the machine. The court explained that “reading a claim in light of the specification, to thereby interpret limitations explicitly recited in the claim, is a quite different thing from ‘reading limitations of the specification into a claim,’ to thereby narrow the scope of the claim by implicitly adding disclosed limitations which have no express basis in the claim.” The court found that applicant was advocating the latter, i.e., the impermissible importation of subject matter from the specification into the claim.). See also *In re Morris*, 127 F.3d 1048, 1054-55, 44 USPQ2d 1023, 1027-28 (Fed. Cir. 1997) (The court held that the PTO is not required, in the course of prosecution, to interpret claims in applications in the same manner as a court would interpret claims in an infringement suit. Rather, the “PTO applies to verbiage of the proposed claims the broadest reasonable meaning of the words in their ordinary usage as they would be understood by one of ordinary skill in the art, taking into account whatever enlightenment by way of definitions or otherwise that may be afforded by the written description contained in applicant’s specification.”).

The broadest reasonable interpretation of the claims must also be consistent with the interpretation that those skilled in the art would reach. *In re Cortright*, 165 F.3d 1353, 1359, 49 USPQ2d 1464, 1468 (Fed. Cir. 1999) (The Board’s construction of the claim limitation “restore hair growth” as requiring the hair to be returned to its original state was held to be an incor-

rect interpretation of the limitation. The court held that, consistent with applicant’s disclosure and the disclosure of three patents from analogous arts using the same phrase to require only some increase in hair growth, one of ordinary skill would construe “restore hair growth” to mean that the claimed method increases the amount of hair grown on the scalp, but does not necessarily produce a full head of hair.).

2111.01 Plain Meaning [R-5]

I. THE WORDS OF A CLAIM MUST BE GIVEN THEIR “PLAIN MEANING” UNLESS **>SUCH MEANING IS INCONSISTENT WITH< THE SPECIFICATION

**>Although< claims of issued patents are interpreted in light of the specification, prosecution history, prior art and other claims, this is not the mode of claim interpretation to be applied during examination. During examination, the claims must be interpreted as broadly as their terms reasonably allow. *In re American Academy of Science Tech Center*, 367 F.3d 1359, 1369, 70 USPQ2d 1827, 1834 (Fed. Cir. 2004) (The USPTO uses a different standard for construing claims than that used by district courts; during examination the USPTO must give claims their broadest reasonable interpretation >in light of the specification<.). This means that the words of the claim must be given their plain meaning unless **>the plain meaning is inconsistent with< the specification. *In re Zletz*, 893 F.2d 319, 321, 13 USPQ2d 1320, 1322 (Fed. Cir. 1989) (discussed below); *Chef America, Inc. v. Lamb-Weston, Inc.*, 358 F.3d 1371, 1372, 69 USPQ2d 1857 (Fed. Cir. 2004) (Ordinary, simple English words whose meaning is clear and unquestionable, absent any indication that their use in a particular context changes their meaning, are construed to mean exactly what they say. Thus, “heating the resulting batter-coated dough to a temperature in the range of about 400°F to 850°F” required heating the dough, rather than the air inside an oven, to the specified temperature.). **

II. IT IS IMPROPER TO IMPORT CLAIM LIMITATIONS FROM THE SPECIFICATION

“Though understanding the claim language may be aided by explanations contained in the written

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or (3) were not published in English under PCT Article 21(2) by WIPO, may not be used to reach back (bridge) to an earlier filing date through a priority or benefit claim for prior art purposes under 35 U.S.C. 102(e).

IV. PARENT'S FILING DATE WHEN REFERENCE IS A CONTINUATION-IN-PART OF THE PARENT

Filing Date of U.S. Parent Application Can Only Be Used as the 35 U.S.C. 102(e) Date If It Supports the **>Subject Matter Relied Upon in the< Child

**>For prior art purposes, a U.S. patent or patent application publication that claims the benefit of an earlier filing date under 35 U.S.C. 120 of a prior non-provisional application would be accorded the earlier filing date as its prior art date under 35 U.S.C. 102(e), provided the earlier-filed application properly supports the subject matter relied upon in any rejection in compliance with 35 U.S.C. 112, first paragraph. In other words, the subject matter used in the rejection must be disclosed in the earlier-filed application in compliance with 35 U.S.C. 112, first paragraph, in order for that subject matter to be entitled to the earlier filing date under 35 U.S.C. 102(e).<

See also MPEP § 706.02(f)(1), examples 2 and 5 to 9.

V. DATE OF CONCEPTION OR REDUCTION TO PRACTICE

35 U.S.C. 102(e) Reference Date Is the Filing Date Not Date of Inventor's Conception or Reduction to Practice

If a reference available under 35 U.S.C. 102(e) discloses, but does not claim the subject matter of the claims being examined or an obvious variant, the reference is not prior art under 35 U.S.C. 102(g). Furthermore, the reference does not qualify as "prior art" under 35 U.S.C. 102 as of a date earlier than its filing date based upon any prior inventive activity that is disclosed in the U.S. patent or U.S. patent application publication in the absence of evidence that the subject matter was actually reduced to practice in this country on an earlier date. See MPEP § 2138. When the cases are not in interference, the effective date of the reference as prior art is its filing date in the United States

(which will include certain international filing dates), as stated in 35 U.S.C. 102(e). See MPEP § 706.02(a). The date that the prior art subject matter was conceived or reduced to practice is of no importance when 35 U.S.C. 102(g) is not at issue. *Sun Studs, Inc. v. ATA Equip. Leasing, Inc.*, 872 F.2d 978, 983, 10 USPQ2d 1338, 1342 (Fed. Cir. 1989) (The defendant sought to invalidate patents issued to Mason and Sohn assigned to Sun Studs. The earliest of these patents issued in June 1973. A U.S. patent to Mouat was found which issued in March 1976 and which disclosed the invention of Mason and Sohn. While the patent to Mouat issued after the Mason and Sohn patents, it was filed 7 months earlier than the earliest of the Mason and Sohn patents. Sun Studs submitted affidavits showing conception in 1969 and diligence to the constructive reduction to practice and therefore antedated the patent to Mouat. The defendant sought to show that Mouat conceived the invention in 1966. The court held that conception of the subject matter of the reference only becomes an issue when the claims of the conflicting patents cover inventions which are the same or obvious over one another. When 35 U.S.C. 102(e) applies but not 35 U.S.C. 102(g), the filing date of the prior art patent is the earliest date that can be used to reject or invalidate claims.).

2136.04 Different Inventive Entity; Meaning of "By Another" [R-1]

IF THERE IS ANY DIFFERENCE IN THE INVENTIVE ENTITY, THE REFERENCE IS "BY ANOTHER"

"Another" means other than applicants, *In re Land*, 368 F.2d 866, 151 USPQ 621 (CCPA 1966), in other words, a different inventive entity. The inventive entity is different if not all inventors are the same. The fact that the application and reference have one or more inventors in common is immaterial. *Ex parte DesOrmeaux*, 25 USPQ2d 2040 (Bd. Pat. App. & Inter. 1992) (The examiner made a 35 U.S.C. 102(e) rejection based on an issued U.S. patent to three inventors. The rejected application was a continuation-in-part of the issued parent with an extra inventor. The Board found that the patent was "by another" and thus could be used in a 35 U.S.C. 102(e)/103 rejection of the application.).

A DIFFERENT INVENTIVE ENTITY IS *PRIMA FACIE* EVIDENCE THAT THE REFERENCE IS “BY ANOTHER”

As stated by the House and Senate reports on the bills enacting section 35 U.S.C. 102(e) as part of the 1952 Patent Act, this subsection of 102 codifies the Milburn rule of *Milburn v. Davis-Bournonville*, 270 U.S. 390 (1926). The Milburn rule authorized the use of a U.S. patent containing a disclosure of the invention as a reference against a later filed application as of the U.S. patent filing date. The existence of an earlier filed U.S. application containing the subject matter claimed in the application being examined indicates that applicant was not the first inventor. Therefore, a U.S. patent, ** a U.S. patent application publication or international application publication, by a different inventive entity, whether or not the application shares some inventors in common with the patent, is *prima facie* evidence that the invention was made “by another” as set forth in *35 U.S.C. < 102(e). *In re Mathews*, 408 F.2d 1393, 161 USPQ 276 (CCPA 1969); *In re Facius*, 408 F.2d 1396, 161 USPQ 294 (CCPA 1969); *Ex parte DesOrmeaux*, 25 USPQ2d 2040 (Bd. Pat. App. & Inter. 1992). See MPEP >§ 706.02(b) and <§ 2136.05 for discussion of methods of overcoming >35 U.S.C. < 102(e) rejections.

2136.05 Overcoming a Rejection Under 35 U.S.C. 102(e) [R-1]

A 35 U.S.C. 102(e) REJECTION CAN BE OVERCOME BY ANTEDATING THE FILING DATE OR SHOWING THAT DISCLOSURE RELIED ON IS APPLICANT'S OWN WORK

When a prior U.S. patent, ** U.S. patent application publication>,< or international application publication* is not a statutory bar, a 35 U.S.C. 102(e) rejection can be overcome by antedating the filing date (see MPEP § 2136.03 regarding critical reference date of 35 U.S.C. 102(e) prior art) of the reference by submitting an affidavit or declaration under 37 CFR 1.131 or by submitting an affidavit or declaration under 37 CFR 1.132 establishing that the relevant disclosure is applicant's own work. *In re Mathews*, 408 F.2d 1393, 161 USPQ 276 (CCPA 1969). The filing date can also be antedated by applicant's earlier foreign priority application or

provisional application if 35 U.S.C. 119 is met and the foreign application or provisional application “supports” (conforms to 35 U.S.C. 112, first paragraph, requirements) all the claims of the U.S. application. *In re Gosteli*, 872 F.2d 1008, 10 USPQ2d 1614 (Fed. Cir. 1989). But a prior application which was not copending with the application at issue cannot be used to antedate a reference. *In re Costello*, 717 F.2d 1346, 219 USPQ 389 (Fed. Cir. 1983). A terminal disclaimer also does not overcome a 35 U.S.C. 102(e) rejection. See, e.g., *In re Bartfeld*, 925 F.2d 1415, 17 USPQ2d 1885 (Fed. Cir. 1991).

See MPEP § 706.02(b) for a list of methods which can be used to overcome rejections based on 35 U.S.C. 102(e) rejections. For information on the required contents of a 37 CFR 1.131 affidavit or declaration and the situations in which such affidavits and declarations are permitted see MPEP § 715. An affidavit or declaration is not appropriate if the reference describes applicant's own work. In this case, applicant must submit an affidavit or declaration under 37 CFR 1.132. See the next paragraph for more information concerning the requirements of 37 CFR 1.132 affidavits and declarations.

A 35 U.S.C. 102(e) REJECTION CAN BE OVERCOME BY SHOWING THE REFERENCE IS DESCRIBING APPLICANT'S OWN WORK

“The fact that an application has named a different inventive entity than a patent does not necessarily make that patent prior art.” *Applied Materials Inc. v. Gemini Research Corp.*, 835 F.2d 279, 15 USPQ2d 1816 (Fed. Cir. 1988). The issue turns on what the evidence of record shows as to who invented the subject matter. *In re Whittle*, 454 F.2d 1193, 1195, 172 USPQ 535, 537 (CCPA 1972). In fact, even if applicant's work was publicly disclosed prior to his or her application, applicant's own work may not be used against him or her unless there is a time bar under 35 U.S.C. 102(b). *In re DeBaun*, 687 F.2d 459, 214 USPQ 933 (CCPA 1982) (citing *In re Katz*, 687 F.2d 450, 215 USPQ 14 (CCPA 1982)). Therefore, when the unclaimed subject matter of a reference is applicant's own invention, applicant may overcome a *prima facie* case based on the patent, ** U.S. patent application publication>,< or international application publication, by showing that the disclosure is a description of applicant's own previous work. Such a

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2136.05 Overcoming a Rejection Under 35 U.S.C. 102(e) [R-1]

A 35 U.S.C. 102(e) REJECTION CAN BE OVERCOME BY ANTEDATING THE FILING DATE OR SHOWING THAT DISCLOSURE RELIED ON IS APPLICANT'S OWN WORK

When a prior U.S. patent, ** U.S. patent application publication>,< or international application publication* is not a statutory bar, a 35 U.S.C. 102(e) rejection can be overcome by antedating the filing date (see MPEP § 2136.03 regarding critical reference date of 35 U.S.C. 102(e) prior art) of the reference by submitting an affidavit or declaration under 37 CFR 1.131 or by submitting an affidavit or declaration under 37 CFR 1.132 establishing that the relevant disclosure is applicant's own work. *In re Mathews*, 408 F.2d 1393, 161 USPQ 276 (CCPA 1969). The filing date can also be antedated by applicant's earlier foreign priority application or

provisional application if 35 U.S.C. 119 is met and the foreign application or provisional application “supports” (conforms to 35 U.S.C. 112, first paragraph, requirements) all the claims of the U.S. application. *In re Gosteli*, 872 F.2d 1008, 10 USPQ2d 1614 (Fed. Cir. 1989). But a prior application which was not copending with the application at issue cannot be used to antedate a reference. *In re Costello*, 717 F.2d 1346, 219 USPQ 389 (Fed. Cir. 1983). A terminal disclaimer also does not overcome a 35 U.S.C. 102(e) rejection. See, e.g., *In re Bartfeld*, 925 F.2d 1415, 17 USPQ2d 1885 (Fed. Cir. 1991).

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showing can be made by proving that the patentee, or ** the inventor(s) of the U.S. patent application publication or the international application publication, was associated with applicant (e.g. worked for the same company) and learned of applicant's invention from applicant. *In re Mathews*, 408 F.2d 1393, 161 USPQ 276 (CCPA 1969). In the situation where one application is first filed by inventor X and then a later application is filed by X & Y, it must be proven that the joint invention was made first, was thereafter described in the sole applicant's patent, or ** was thereafter described in the sole applicant's U.S. patent application publication or international application publication, and then the joint application was filed. *In re Land*, 368 F.2d 866, 151 USPQ 621 (CCPA 1966).

In *In re Land*, separate U.S. patents to Rogers and to Land were used to reject a joint application to Rogers and Land under 35 U.S.C. 102(e)/103. The inventors worked for the same company (Polaroid) and in the same laboratory. All the patents flowed from the same research. In addition, the patent applications were prepared by the same attorneys, were interrelated and contained cross-references to each other. The court affirmed the rejection because (1) the inventive entities of the patents (one to Rogers and one to Land) were different from the inventive entity of the joint application (Rogers and Land) and (2) Land and Rogers brought their knowledge of their individual work with them when they made the joint invention. There was no indication that the portions of the references relied on disclosed anything they did jointly. Neither was there any showing that what they did jointly was done before the filing of the reference patent applications.

See also *In re Carreira*, 532 F.2d 1356, 189 USPQ 461 (CCPA 1976) (The examiner rejected claims to a joint application to Carreira, Kyrakakis, Solodar, and Labana under 35 U.S.C. 102(e) and 103 in view of a U.S. patent issued to Tulagin and Carreira or a patent issued to Clark. The applicants submitted declarations under 37 CFR 1.132 by Tulagin and Clark in which each declarant stated he was "not the inventor of the use of compounds having a hydroxyl group in a position ortho to an azo linkage." The court held that these statements were vague and inconclusive because the declarants did not disclose the use of this generic

compound but rather species of this generic compound in their patents and it was the species which met the claims. The declaration that each did not invent the use of the generic compound does not establish that Tulagin and Clark did not invent the use of the species.)

MPEP § 715.01(a), § 715.01(c), and § 716.10 set forth more information pertaining to the contents and uses of affidavits and declarations under 37 CFR 1.132 for antedating references. See MPEP § 706.02(l)(1) for information pertaining to rejections under 35 U.S.C. 102(e)/103 and the applicability of 35 U.S.C. 103(c).

APPLICANT NEED NOT SHOW DILIGENCE OR REDUCTION TO PRACTICE WHEN THE SUBJECT MATTER DISCLOSED IN THE REFERENCE IS APPLICANT'S OWN WORK

When the reference reflects applicant's own work, applicant need not prove diligence or reduction to practice to establish that he or she invented the subject matter disclosed in the reference. A showing that the reference disclosure arose from applicant's work coupled with a showing of conception by the applicant before the filing date of the reference will overcome the 35 U.S.C. 102(e) rejection. The showing can be made by submission of an affidavit by the inventor under 37 CFR 1.132. The other patentees need not submit an affidavit disclaiming inventorship, but, if submitted, a disclaimer by all other patentees should be considered by the examiner. *In re DeBaun*, 687 F.2d 459, 214 USPQ 933 (CCPA 1982) (Declaration submitted by DeBaun stated that he was the inventor of subject matter disclosed in the U.S. patent reference of DeBaun and Noll. Exhibits were attached to the declaration showing conception and included drawings DeBaun had prepared and given to counsel for purposes of preparing the application which issued as the reference patent. The court held that, even though the evidence was not sufficient to antedate the prior art patent under 37 CFR 1.131, diligence and/or reduction to practice was not required to show DeBaun invented the subject matter. Declarant's statement that he conceived the invention first was enough to overcome the 35 U.S.C. 102(e) rejection.).

CLAIMING OF INDIVIDUAL ELEMENTS OR SUBCOMBINATIONS IN A COMBINATION CLAIM OF THE REFERENCE DOES NOT ITSELF ESTABLISH THAT THE PATENTEE INVENTED THOSE ELEMENTS

The existence of combination claims in a reference is not evidence that the patentee invented the individual elements or subcombinations included if the elements and subcombinations are not separately claimed apart from the combination. *In re DeBaun*, 687 F.2d 459, 214 USPQ 933 (CCPA 1982) (citing *In re Facius*, 408 F.2d 1396, 1406, 161 USPQ 294, 301 (CCPA 1969)).

See also *In re Mathews*, 408 F.2d 1393, 161 USPQ 276 (CCPA 1969) (On September 15, 1961, Dewey filed an application disclosing and claiming a time delay protective device for an electric circuit. In disclosing the invention, Dewey completely described, but did not claim, a “gating means 19” invented by Mathews which was usable in the protective device. Dewey and Mathews were coworkers at General Electric Company, the assignee. Mathews filed his application on March 7, 1963, before the Dewey patent issued but almost 18 months after its filing. The Mathews application disclosed that “one illustration of a circuit embodying the present invention is shown in copending patent application S.N. 138,476-Dewey.” The examiner used Dewey to reject all the Mathews claims under 35 U.S.C. 102(e). In response, Mathews submitted an affidavit by Dewey under 37 CFR 1.132. In the affidavit, Dewey stated that he did not invent the gating means 19 but had learned of the gating means through Mathews and that GE attorneys had advised that the gating means be disclosed in Dewey’s application to comply with 35 U.S.C. 112, first paragraph. The examiner argued that the only way to overcome a 35 U.S.C. 102(e) rejection was by submitting an affidavit or declaration under 37 CFR 1.131 to antedate the filing date of the reference. The court reversed the rejection, holding that the totality of the evidence on record showed that Dewey derived his knowledge from Mathews who is “the original, first and sole inventor.”).

2137 35 U.S.C. 102(f)

35 U.S.C. 102. Conditions for patentability; novelty and loss of right to patent.

A person shall be entitled to a patent unless -

(f) he did not himself invent the subject matter sought to be patented.

Where it can be shown that an applicant “derived” an invention from another, a rejection under 35 U.S.C. 102(f) is proper. *Ex parte Kusko*, 215 USPQ 972, 974 (Bd. App. 1981) (“most, if not all, determinations under section 102(f) involve the question of whether one party derived an invention from another”).

While derivation will bar the issuance of a patent to the deriver, a disclosure by the deriver, absent a bar under 35 U.S.C. 102(b), will not bar the issuance of a patent to the party from which the subject matter was derived. *In re Costello*, 717 F.2d 1346, 1349, 219 USPQ 389, 390-91 (Fed. Cir. 1983) (“[a] prior art reference that is not a statutory bar may be overcome by two generally recognized methods”: an affidavit under 37 CFR 1.131, or an affidavit under 37 CFR 1.132 “showing that the relevant disclosure is a description of the applicant’s own work”); *In re Facius*, 408 F.2d 1396, 1407, 161 USPQ 294, 302 (CCPA 1969) (subject matter incorporated into a patent that was brought to the attention of the patentee by applicant, and hence derived by the patentee from the applicant, is available for use against applicant unless applicant had actually invented the subject matter placed in the patent).

Where there is a published article identifying the authorship (MPEP § 715.01(c)) or a patent identifying the inventorship (MPEP § 715.01(a)) that discloses subject matter being claimed in an application undergoing examination, the designation of authorship or inventorship does not raise a presumption of inventorship with respect to the subject matter disclosed in the article or with respect to the subject matter disclosed but not claimed in the patent so as to justify a rejection under 35 U.S.C. 102(f). However, it is incumbent upon the inventors named in the application, in reply to an inquiry regarding the appropriate inventorship under subsection (f), or to rebut a rejection under 35 U.S.C. 102(a) or (e), to provide a satisfactory showing by way of affidavit under 37 CFR 1.132 that the inventorship of the application is correct in that the reference discloses subject matter invented by the applicant rather than derived from the author or patentee notwithstanding the authorship of the article or the inventorship of the patent. *In re Katz*,

(which ordinarily accompanies the order) and any subsequent reexamination prosecution should be on the basis of the claims as amended by any copending reexamination or reissue proceeding.

2644 Prior Art on Which the Determination Is Based [Added R-2]

The determination of whether or not “a substantial new question of patentability” is present can be based upon any prior art patents or printed publications. 35 U.S.C. 312(a) provides that the determination on a request will be made “with or without consideration of other patents or printed publications,” i.e., other than those relied upon in the request. The examiner is not limited in making the determination based on the patents and printed publications relied upon in the request. The examiner can find “a substantial new question of patentability” based upon the prior art patents or printed publications relied upon in the request, a combination of the prior art relied upon in the request and other prior art found elsewhere, or based entirely on different patents or printed publications. The primary source of patents and printed publications used in making the determination are those relied on in the request. For reexamination ordered on or after November 2, 2002, see MPEP § 2642, subsection II.A. for a discussion of “old art.” The examiner can also consider any patents and printed publications of record in the patent file from submissions under 37 CFR 1.501 which are in compliance with 37 CFR 1.98 in making the determination. If the examiner believes that additional prior art patents and publications can be readily obtained by searching to supply any deficiencies in the prior art cited in the request, the examiner can perform such an additional search. Such a search should be limited to that area most likely to contain the deficiency of the prior art previously considered and should be made only where there is a reasonable likelihood that prior art can be found to supply any deficiency necessary to “a substantial new question of patentability.”

The determination should be made on the claims in effect at the time the determination is made. 37 CFR 1.923.

2646 Decision Ordering Reexamination [R-7]

35 U.S.C. 313. Inter partes reexamination order by Director

If, in a determination made under section 312(a), the Director finds that a substantial new question of patentability affecting a claim of a patent is raised, the determination shall include an order for inter partes reexamination of the patent for resolution of the question. The order may be accompanied by the initial action of the Patent and Trademark Office on the merits of the inter partes reexamination conducted in accordance with section 314.

37 CFR 1.931. Order for inter partes reexamination

(a) If a substantial new question of patentability is found, the determination will include an order for *inter partes* reexamination of the patent for resolution of the question.

(b) If the order for *inter partes* reexamination resulted from a petition pursuant to § 1.927, the *inter partes* reexamination will ordinarily be conducted by an examiner other than the examiner responsible for the initial determination under § 1.923.

If a request for reexamination is granted, the examiner's decision granting the request will conclude that a substantial new question of patentability has been raised by (A) identifying all claims and issues, (B) identifying the patents and/or printed publications relied upon, and (C) providing a brief statement of the rationale supporting each new question.

In the examiner's decision, the examiner must identify at least one substantial new question of patentability and explain how the prior art patents and/or printed publications raise that question. In a simple case, this may entail adoption of the reasons provided by the third party requester. The references relied on by the examiner should be cited on a PTO-892 form, unless already listed on a form PTO/SB/08A or 08B, or PTO/SB/42 (or on a form having a format equivalent to one of these forms) submitted by the third party requester. A copy of the reference should be supplied only where it has not been previously supplied to the patent owner and third party requester.

As to each substantial new question of patentability identified in the decision, the decision should point out:

- (A) The prior art patents and printed publications which add some new teaching as to at least one claim;
- (B) What that new teaching is;
- (C) The claims that the new teaching is directed to;

(D) That the new teaching was not previously considered nor addressed in the prior examination of the patent or a final holding of invalidity by the Federal Courts;

(E) That the new teaching is such that a reasonable examiner would consider the new teaching to be important in deciding to allow the claim being considered; and

(F) Where the question is raised, or where it is not clear that a patent or printed publication pre-dates the patent claims, a discussion should be provided as to why the patent or printed publication is deemed to be available against the patent claims.

If arguments are raised by the third party requester as to grounds not based on patents or printed publications, such as those based on public use or on sale under 35 U.S.C. 102(b), or abandonment under 35 U.S.C. 102(c), the examiner should note that such grounds are improper for reexamination and are not considered or commented upon. See 37 CFR 1.906(c).

In the decision on the request, the examiner will not decide, and no statement should be made as to, whether the claims are rejected over the patents and printed publications. The examiner does not decide on the question of patentability of the claims in the decision on the request. The examiner only decides whether there is a substantial new question of patentability to grant the request to order reexamination.

The decision granting the request is made using form PTOL-2063 as a cover sheet. See MPEP § 2647.01 for an example of a decision granting a request for *inter partes* reexamination.

Form Paragraph 26.01 should be used at the beginning of each decision letter granting reexamination.

¶ 26.01 New Question of Patentability

A substantial new question of patentability affecting claim [1] of United States Patent Number [2] is raised by the present request for *inter partes* reexamination.

Extensions of time under 37 CFR 1.136(a) will not be permitted in *inter partes* reexamination proceedings because the provisions of 37 CFR 1.136 apply only to “an applicant” and not to the patent owner in a reexamination proceeding. Additionally, 35 U.S.C. 314(c) requires that *inter partes* reexamination proceedings “will be conducted with special dispatch” (37 CFR 1.937). Patent owner extensions of time in *inter partes* reexamination proceedings are provided for in 37 CFR 1.956. Extensions of time are not available for third party requester comments, because a comment period of 30 days from service of patent owner’s response is set by statute. 35 U.S.C. 314(b)(3).

Form paragraph 26.73 should be used at the end of each decision letter granting reexamination that is not being mailed concurrently with the first Office action on patentability (see MPEP § 2660).

¶ 26.73 Correspondence and Inquiry as to Office Actions

All correspondence relating to this *inter partes* reexamination proceeding should be directed:

By Mail to: Mail Stop *Inter Partes* Reexam
Attn: Central Reexamination Unit
Commissioner for Patents
United States Patent & Trademark Office
P.O. Box 1450
Alexandria, VA 22313-1450

By FAX to: (571) 273-9900
Central Reexamination Unit

By hand: Customer Service Window
Randolph Building
401 Dulany Street
Alexandria, VA 22314

Any inquiry concerning this communication or earlier communications from the examiner, or as to the status of this proceeding, should be directed to the Central Reexamination Unit at telephone number (571) 272-7705.

I. PANEL REVIEW CONFERENCE

After an examiner has determined that the reexamination proceeding is ready for granting reexamination, the examiner will formulate a draft preliminary order granting reexamination. The examiner will then inform his/her **>Central Reexamination Unit (CRU) Supervisory Patent Examiner (SPE)<** of his/her intent to issue an order granting reexamination. The **>CRU SPE<** will convene a panel review conference, and the conference members will review the matter. See MPEP § 2671.03 for the make-up of the panel. If the conference confirms the examiner’s preliminary decision to grant reexamination, the proposed order granting reexamination shall be issued and signed by the examiner, with the two other conferees initialing the action (as “conferee”) to indicate their presence in the conference. If the conference does not confirm the examiner’s preliminary decision, the examiner will reevaluate and issue an appropriate communication.

II. PETITION TO VACATE THE ORDER GRANTING REEXAMINATION

A substantive determination by the Director of the Office to institute reexamination pursuant to a finding

OPTIONAL INTER PARTES REEXAMINATION

2646

that the prior art patents or printed publications raise a substantial new question of patentability is not subject to review by petition or otherwise. See *Joy Mfg. Co. v. Nat'l Mine Serv. Co., Inc.*, 810 F.2d 1127, 1 USPQ2d 1627 (Fed. Cir. 1987); *Heinl v. Godici*, 143 F.Supp. 2d 593 (E.D. Va. 2001). Note further the decision of *Patlex Corp. v. Quigg*, 680 F.Supp. 33, 6 USPQ2d 1296, 1298 (D.D.C. 1988) (the legislative scheme leaves the Director's 35 U.S.C. 303 determination entirely to his discretion and not subject to judicial review). These decisions were rendered for *ex parte* reexamination; however, the holdings of these decisions apply equally in *inter partes* reexamination proceedings, since the language of 35 U.S.C. 302(c) (i.e., the *ex parte* reexamination statute) is also found in 35 U.S.C. 312(c) (i.e., the *inter partes* reexamination statute). Because the substantive determination is not subject to review by petition or otherwise, neither the patent owner nor the third party requester has a right to petition, or request reconsideration of, a finding that the prior art patents or printed publications raise a substantial new question. There is no right to petition such a finding even if the finding of a substantial new question is based on reasons other than those urged by the third party requester (or based on less than all the grounds urged by the third party requester). Where the examiner determines that a date of a reference is early enough such that the reference constitutes prior art, that determination is not petitionable (with respect to vacating the examiner's finding of a substantial new question). Where the examiner determines that a reference is a printed publication (i.e., that the criteria for publication has been satisfied), that determination is also not petitionable. These matters cannot be questioned with respect to vacating the order granting reexamination until a final agency decision on the reexamination proceeding has issued. Rather, these matters can be argued by the patent owner and appealed during the examination phase of the reexamination proceeding.

A petition under 37 CFR 1.181 may, however, be filed to vacate an *ultra vires* reexamination order, such as where the order for reexamination is not based on prior art patents and printed publications. In cases where no discretion to grant a request for reexamination exists, a petition to vacate the decision to grant, or a request for reconsideration, will be entertained.

"Appropriate circumstances" under 37 CFR 1.181(a)(3) exist to vacate the order granting reexamination where, for example:

(A) the reexamination order is not based on prior art patents or printed publications;

(B) reexamination is prohibited under 37 CFR 1.907;

(C) all claims of the patent were held to be invalid by a final decision of a Federal Court after all appeals;

(D) reexamination was ordered for the wrong patent;

(E) reexamination was ordered based on a duplicate copy of the request; or

(F) the reexamination order was based **wholly** on the same question of patentability raised by the prior art *previously considered* in an earlier concluded examination of the patent by the Office (e.g., the application which matured into the patent, a prior reexamination, an interference proceeding).

As to (F), the decision of *In re Recreative Technologies Corp.*, 83 F.3d 1394, 38 USPQ2d 1776 (Fed. Cir. 1996) is to be noted. See the discussion in MPEP § 2642, subsection II.A. as to the criteria for vacating a reexamination order in view of the decision.

When a petition under 37 CFR 1.181 is filed to vacate a reexamination order, the third party requester may file a single submission in opposition to the petition. Because reexamination proceedings are conducted with special dispatch, 35 U.S.C. 314(c), any such opposition by the third party requester must be filed within two weeks of the date upon which a copy of the original 37 CFR 1.181 petition was served on the third party requester to ensure consideration. It is advisable that, upon receipt and review of the served copy of such a 37 CFR 1.181 petition which the third party requester intends to oppose, the requester should immediately place a courtesy telephone call to the **>CRU SPE< to notify the Office that an opposition to the 37 CFR 1.181 petition will be filed. Whenever possible, filing of the opposition should be submitted by facsimile transmission.

The filing of a 37 CFR 1.181 petition to vacate an *ultra vires* reexamination order is limited to a single submission, even if an opposition thereto is filed by a third party requester.

III. PRIOR ART SUBMITTED AFTER THE ORDER

Any prior art citations under 37 CFR 1.501 submitted after the date of the decision ordering *inter partes* reexamination should be retained in a separate file by the Technology Center (TC) (usually the TC Quality Assurance Specialist (QAS)) and stored until the reexamination proceeding is concluded, at which time the prior art citation is then entered of record in the patent file. See MPEP § 2206. Note that 37 CFR 1.902 governs submissions of prior art that can be made by *patent owners* and *third party requesters* after reexamination has been ordered.

2647 Decision Denying Reexamination [R-7]

The request for reexamination will be denied if a substantial new question of patentability is not found based on patents or printed publications.

If the examiner concludes that no substantial new question of patentability has been raised, the examiner should prepare a decision denying the reexamination request. Form paragraph 26.02 should be used as the introductory paragraph in a decision denying reexamination.

¶ 26.02 No New Question of Patentability

No substantial new question of patentability is raised by the present request for *inter partes* reexamination and the prior art cited therein for the reasons set forth below.

The decision denying the request will then indicate, for each patent or publication cited in the request, why the citation:

(A) Is cumulative to the teachings of the art cited in the earlier concluded examination of the patent;

(B) Is not available against the claims (e.g., the reference is not available as prior art because of its date or the reference is not a publication);

(C) Would not be important to a reasonable examiner. Even if the citation is available against the claims and it is not cumulative, it still cannot be the basis for a substantial new question of patentability if the additional teaching of the citation would not be important to a reasonable examiner in deciding whether any claim (of the patent for which reexamination is requested) is patentable; or

(D) Is one which was cited in the record of the patent and is barred by the guidelines set forth in MPEP § 2642, subsection II.A.

The examiner should also, in the decision, respond to the substance of each argument raised by the third party requester which is based on patents or printed publications.

If arguments are presented as to grounds not based on prior art patents or printed publications, such as those based on public use or on sale under 35 U.S.C. 102(b), or abandonment under 35 U.S.C. 102(c), the examiner should note that such grounds are improper for reexamination and are not considered or commented upon. See 37 CFR 1.906(c).

See MPEP § 2647.01 for an example of a decision denying a request for *inter partes* reexamination.

The decision denying the request is mailed by the Central Reexamination Unit (CRU), and jurisdiction over the reexamination proceeding is retained by the CRU to await any petition seeking review of the examiner's determination refusing reexamination. If such a petition is not filed within one (1) month of the examiner's determination denying reexamination, the CRU then processes the reexamination file to provide the partial refund set forth in 37 CFR 1.26(c) (the Office of Finance no longer processes reexamination proceedings for a refund).

The reexamination proceeding is then given a 420 status. A copy of the PALM "Application Number Information" screen and the "Contents" screen is printed, the printed copy is annotated by adding the comment "PROCEEDING CONCLUDED," and the annotated copy is then scanned into IFW using the miscellaneous letter document code.

The concluded reexamination file (electronic or paper) containing the request and the decision denying the request becomes part of the patent's record.

PANEL REVIEW CONFERENCE

After an examiner has determined that the reexamination proceeding is ready for denying reexamination, the examiner will formulate a draft preliminary order denying reexamination. The examiner will then inform his/her CRU Supervisory Patent Examiner (SPE) of his/her intent to issue an order denying reexamination. The CRU SPE will convene a panel review conference, and the conference members will review the matter. See MPEP § 2671.03 for the